



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,390	07/29/2005	Yong-Hoon Chung	5252MC-1	7628
23442	7590	09/03/2008		
SHERIDAN ROSS PC 1560 BROADWAY SUITE 1200 DENVER, CO 80202			EXAMINER WOODWARD, CHERIE MICHELLE	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 09/03/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/519,390

**Applicant(s)**

CHUNG ET AL.

**Examiner**

CHERIE M. WOODWARD

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 38, 41, 42 and 76-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38, 41, 76 and 77 is/are rejected.
- 7) ☒ Claim(s) 42 and 78 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/11/2008 has been entered.

### ***Formal Matters***

2. Claims 1-37, 39-40, and 43-75 have been cancelled by Applicant. New claims 76-78 have been added. Claims 38, 41, 42, and 76-78 are pending and under examination.

### ***Response to Arguments***

#### ***Claim Rejections Withdrawn***

3. Rejections over cancelled claims are withdrawn as moot.
4. The rejection of claims 38, 41, and 42 under 35 U.S.C. 112, second paragraph, is withdrawn in light of Applicant's amendments.
5. The rejection of claim 38 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in light of Applicant's amendments.

### ***Objections/Rejections Maintained***

6. The objection to the title of the invention is maintained for the reasons of record, but will be held in abeyance. Applicant has indicated that the title will be changed when allowable subject matter is identified (see Remarks, filed 28 May 2007, p. 9 of 13).

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

Art Unit: 1647

patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 38, 41, and 42 remain rejected and new claims 76 and 77 are rejected under 35 U.S.C. 102(e) as being anticipated by Roberts et al., US Patent Application Publication 20050220800 (published 24 August 2005, benefit to 1 May 2002) (previously cited of record).

The '800 publication teaches a TPO variant comprising F141V at paragraph 160 (see also Figure 9). A composition comprising the protein is taught at paragraph 25 and claim 31.

Applicant argues that the '800 publication discloses methods for producing protein variants having reduced allergenicity, whereas the present invention does not use the same method steps as the '800 publication (Remarks, page 8, second and third paragraphs). Applicant's arguments have been fully considered, but they are not persuasive.

Applicant is arguing about differences in method steps when the instant claims are drawn to a composition – a protein variant which substitutes a valine residue for a phenylalanine residue in TPO (as elected) and a pharmaceutical composition comprising the claimed TPO variant. The '800 teaches the claimed TPO variant and pharmaceutical composition and therefore anticipates the instant claims.

#### ***Allowable Subject Matter***

9. Claims 42 and 78, as drawn to the elected species of TPO are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The TPO substitution mutant of F131V based on the amino acid sequence of SEQ ID NO: 25 is free of the prior art. Applicant is reminded that the election of TPO was made without traverse (see Response to Restriction/Election, filed 9/15/2006).

#### ***Conclusion***

Claims 38, 41, 76, and 77 are rejected.

Claims 42 and 78 are objected to.

The title remains objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

Art Unit: 1647

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/  
Examiner, Art Unit 1647